DETAILED ACTION

The receipt of Applicant's list of claims remarks dated 1/20/2010 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 24 recites "evaluating the lean body mass and fat body mass of the infant after feeding the infant feeding the infant the nutritional formula." The specification supports only evaluating lean body mass and fat body mass in "**preterm infants**". There is no support for evaluating an "**infant**" which is a broader embodiment of the described preterm infants.

In accordance with MPEP 714.02 applicants should specifically point out support for the generic concept of claim 1 using the expression "evaluating the lean body mass and fat body mass of the infant after feeding the infant feeding the infant the nutritional formula."

In view of Applicant's arguments, the rejections that are not reiterated in the current Office Action are hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 1-10 and 12-23 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Connor et al. US publication 20020045660 (O'Connor).

O'Connor teaches improved nutritional composition containing specified amounts of DHA and AA as well as their precursor essential fatty acids alpha-linolenic and linoleum acids. The methods involve feeding LCP supplemented, nutrient-enriched formulas for an extended feeding regimen, typically until at least 3 months corrected age (CA), preferably to 6 or even 12 months CA. The neurological developments such as visual development, and motor development were enhanced without findings of anthropometric growth faltering or inhibition (abstract). Note that the lean body mass is mainly muscles and the motor development depends on muscles' mass.

O'Connor teaches also that infant formula is intended for full-term infants [0088], and recommends using enriched formula comprising DHA and AA for pre-term infants (abstract). O'Connor's formula contains the same amounts recited in the instant claims such as about 2-65 mg/kg body wt. of DHA and preferred 3-20 mg/kg body wt. and an amount of AA of 5-65 mg/kg body wt. preferred 5-40 mg/kg body wt. the formula is

intended for infants of less than one year corrected age (See table "C" and claims 16 and 17). O'Connor discloses the values of caloric densities in different units; however, it is expected to be the same since the reference discloses the same compounds in the same amounts. Also instant claims 8 and 9 recite the amount of grams per each 100kcal of the formula which is also inherent since the reference discloses same amounts and percentages of kcal's. The protein, fat and carbohydrate components provide, respectively, from about 8 to 10, 46 to 50 and 41 to 44% of the calories; and the caloric density ranges narrowly from about 660 to about 700 kcal/L [0088]. Regarding claims 12-14 that recite amount of DHA and AA as a percentage of the total fatty acids in the formula, O'Connor describes similar percentages [0088].

Limiting the infants to preterm infants, reciting all the results of administering the ARA and DHA in a formula would not differentiate the instant claims over the prior art is disclosed by O'Connor (abstract).

O'Connor discloses a formula comprising the same fatty acids for improving the neurological and motor development, though the reference does not disclose literally the effect of a formula comprising DHA and AA on the growth of lean mass or the reduction of fat mass, it is noted that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding instant claim 16, it is noted that evaluating infant

growth is done periodically as a routine and was done and disclosed by O'Connor (see tables).

New claim 23 is properly anticipated by O'Connor because the reference discloses administering a formula for infants comprising ARA and ADA which is required by the claim. The effect of the formula administered as to increase lean body mass and reduce fat body mass is inherent.

Response to Arguments

Applicant's arguments filed 1/20/2010 have been fully considered but they are not persuasive. Applicant argues that:

- O'Connor, et al. fail to disclose or suggest feeding a nutritional formula comprising DHA and ARA to a preterm infant for the purpose of increasing lean body mass and reducing fat body mass in the infant, as required by claim 1. O'Connor, et al. state that the ARA and DHA supplemented formulas described therein may improve or enhance neurological development, such as visual, motor, and language development, but do not disclose or suggest that such formulas have any effect on body composition, such as increasing lean body mass and reducing fat body mass.

- **This was not found persuasive because** administering the same formula to the same population (infants) should produce the same results. Even if the reference did not disclose literally these results, the reference clearly teaches that the formula enhances healthy growth. In addition, the results of increasing lean body mass and decreasing fat body mass cannot be avoided by any means since it is the result of the

only step required for this instant method which is administering the formula comprising ARA and DHA to premature infants.

- It is respectfully submitted that whether or not the nutritional formulas of O'Connor, et al. inherently result in an increase in lean body mass and a reduction in fat body mass when fed to an infant is irrelevant to determining if O'Connor, et al. inherently discloses applicants' claimed method.

- **To respond** to Applicant, the Office does not argue that the method is inherent. However, the method in O'Connor and the instant method are the same, administering to infants a formula comprising AA and DHA. The inherency is made known in the results which should result from the same method disclosed in O'Connor.

- Applicants' claim 1 specifically requires the nutritional formula comprising DHA and ARA be administered to the infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. Thus, in order to anticipate applicants' claim 1, O'Connor, et al. must also disclose, either expressly or inherently, a method wherein a nutritional formula comprising DHA and ARA is administered to a preterm infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. This is a limitation of applicants' claim 1 that cannot be ignored.

- **To respond,** it is respectfully noted that in claim 1, reciting "increasing lean body mass and reducing fat body mass in infants" is included in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural

limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In the instant case, the preamble did not lead to any changes in the structure of the infant formula disclosed by the prior art. Therefore, in addition to the fact that the results are inherent, the preamble would not be accorded a patentable weight.

- Applicants further note that a finding of inherency cannot be based on mere assumptions by the Office. Rather, to establish inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.. Furthermore, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Applicant cites *Ex parte Levy, In re Rijckaert,* and *In re Robertson* to support the arguments.

- This was not found persuasive because:

I*n Ex parte Levy,* the prior art used was not the same as recited in the claims, therefore, the Board reversed on the basis that objective evidence should be provided for inherency. This is not the situation in the current rejection because, the composition used in the method is the same (formula containing AA and ADA), the population received the formula is the same (infants). There is nothing that the Examiner introduced from the prior art that is like or similar to the instant claims to require evidence. The method has the same step is administering, and the composition is the same formula containing AA and ADA.

In re Rijckaert, the court did not support the Office rejection because inherency was based on what would result due to optimization of conditions. This is not the case in the current Office Action; no optimization was viewed or argued.

In re Robertson, the rejection was reversed also because; the rejection was based on optimization which is not the case in the instant Office Action.

Therefore, the cited cases are not the same as the current situation and the decisions cannot be applied to the current arguments.

However, it is the position of the Examiner that the best application of court cases to the instant situation is *In re Best*, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (MPEP 2112).

- In response to Examiner's statement that the motor system includes muscles as well as nerves, stating that nowhere do O'Connor, et al. indicate that "growth" has anything to do with increasing lean muscle mass and reducing fat body mass.
- In this regard, Applicant is correct that O'Connor disclosure seems to limit motor development to the neurological development only and the response is persuasive.

Thus, claims 1-9 and 12-16 remain anticipated since each and every element in the claim is found expressly or inherently described in O'Connor.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9 and 12-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al. US publication 20020045660 in view of Thierry Raclot et al. "Site-specific Regulation of Gene Expression by - Polyunsaturated Fatty Acids in Rat White Adipose Tissue" Journal of Lipid Research, Vo. 38, 1997 Pages 1963-1972 (Racolt), the reference was provided by Applicant in the IDS dated 8/7/2006.

O'Connor is relied upon for the reasons set forth hereinabove. O'Connor is inherently having the effect of reducing fat mass and increasing lean body mass.

The reference did not teach literally that long chain polyunsaturated fatty acids reduce fat body mass.

Raclot studied the effect of dietary n-3 PUFAs given as eicosapentaenoic acid (EPA group), decosahexaenoic acid (DHA group). The reference concluded that n-3 PUFAs limit abdominal fat depot hypertrophy.

Thus, it would have been obvious to a person having ordinary skill in the art the include the long chain the fatty acids ARA and DHA in a premature infant formula to achieve the increase of the muscular tissue while limiting the increase in fat cell size as disclosed by the combination of O'Connor and Racolt. The artisan would expect success in making a formula for infants specifically premature infants who are in need for healthy compensatory growth.

Response to Arguments

Applicant's arguments filed 1/20/2010 have been fully considered but they are not persuasive. Applicant argues that:

- Applicant argues that O'Connor fails to disclose or suggest feeding a nutritional formula comprising a source of DHA and ARA to an infant for the purpose of increasing lean body mass and reducing fat body mass.
- This was not found persuasive because administering the same formula to the same population (infants) should produce the same results. Even if the reference did not disclose literally these results, the results, which are increasing lean body mass and decreasing fat body mass cannot be avoided by any means since it is the result of the only step required for this instant method which is administering the formula comprising ARA and DHA to full term and premature infants.

Raclot, et al. fail to disclose or suggest feeding a preterm infant a nutritional formula comprising DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant, as required by claim 1 nor do Raclot, et al. disclose or suggest that nutritional formulas comprising the combination of ARA and DHA increase lean body mass and reduce fat body mass generally.

- This was not found persuasive because Raclot was relied upon for teaching that n-3 PUFAs limit abdominal fat depot hypertrophy. However, O'Connor is the primary reference which discloses the limitations argued by Applicant.
- Specifically, to reject a claim based on this rationale, the Office must articulate the following: (i) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was

reasonable expectation of success; and (3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

- To respond to Applicant, the Examiner likes to avoid copying the obviousness rejection and pasting it in this response. In summary, (1) O'Connor teaches administering a formula comprising AA and ADA from fish/fungal sources to premature and full-term infants. These are the limitations required by instant claims. The effect of such formula is inherent, and expected. It is not novel or non-obvious to claim an undiscovered result of the same method. (2) A person having ordinary skill in the art should expect success in reducing fat body mass and increasing lean body mass because Raclot teaches that that n-3 PUFAs limit abdominal fat depot hypertrophy. (3)

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to evaluating the body mass index routinely as a routine and recognize the advantages of administering a formula comprising AA and ADA on the lean body mass and fat body mass which is inherently gained by administering the formula disclosed by O'Connor and Raclot. The artisan would expect success in making a formula for infants specifically premature infants who are in need for healthy compensatory growth. This statement is to explain a conclusion of obviousness.

Note that the results of the same method are inherent and expected. If Applicant believes that O'Connor's formula administered to infants is not able to increase lean body mass and reduce fat body mass, then, the burden is on Applicant to prove how can the instant same formula achieve this effect? It is

also noted that Raclot is relied upon for teaching "literally" the effect of n-3 PUFA's in limiting abdominal fat depot hypertrophy.

- There is no apparent reason for one skilled in the art to modify the cited references to arrive at applicants' claimed.

To respond: in the current case, no modification is needed since O'Connor used the same formula. Obviousness is shown in the instant case in showing that the art was well aware of the effect of n-3 PUFA's on body fat and the motivation is to emphasize evaluation of the results of the method practiced by O'Connor, wherein the results on the lean and fat in the body was explained by Raclot and the motivation for evaluating the body mass index well known in the art (as an evidence see for example JCK Wells, A Hattori chart analysis of body mass index in infants and children, International Journal of Obesity (2000) 24, 325-329). The reference discloses that there is a continued emphasis on BMI (body mass index) for routine assessment of body fat in individuals risks failing to identify both excess fatness and its risk factors in the pediatric population.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 9:00AM - 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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